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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/559,407 | 12/05/2005 | Yun-Hee Ku | P5102/JRIM | 5617 |
| 41943 | 7590 | 03/13/2008 | EXAMINER | |
| GWIPS | | | STOCK JR, GORDON J | |
| Peter T. Kwon | | | | |
| Gwacheon P.O. Box 72 | | | ART UNIT | PAPER NUMBER |
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| KOREA, REPUBLIC OF | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/559,407 | KU, YUN-HEE | |
| | Examiner | Art Unit | |
| | GORDON J. STOCK JR | 2877 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 January 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-10 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 05 December 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. The Amendment received on January 28, 2008 has been entered into the record.

Drawings and Specification

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lack of a screen of **claim 8** wherein said image capturing unit directly captures diffracted images must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The specification is objected to for the following: on page 3 lines 20-21, page 7 lines 5-7, and page 8 lines 17-18 ‘for calculating the blood cell deformability, variation of the shearing

force, and deformation on time based on data' should be corrected to adequately convey what is being calculated such as merely a deformation index and shearing force (stress)(see rejection of **claim 1** under 35 U.S.C. 112 first paragraph below). In addition, it appears that 'on time based on data' should read –on time based data-. Corrections required.

4. The specification is objected to for the following: on page 4 lines 7-8 'such as a silicon, silica, quartz, glass, polymer produced by laser, extruded polymer, or ceramics' should read—such as silicon, silica, quartz, glass, a polymer produced by a laser, an extruded polymer, or ceramics-. Corrections required.

5. The specification is objected to for the following: on page 12 line 17 'A' and 'B' of Equation 1 are not defined. Correction is required.

Claim Objections

6. **Claim 1** is objected to for the following: on line 13 'the diffracted images' lacks antecedent basis. Examiner suggests -diffracted images-. In addition, on line 14 'diffracted images' should read -the diffracted images-. On line 15 'the shearing force' lacks antecedent basis. Examiner suggests –a sheering force-. And on line 15 'in time based on data' appears to need correction to -on time based data-. Corrections required.

7. **Claim 2** reads -generating vacuum (negative) pressure at the waste blood pot-. Examiner suggests using -generating vacuum pressure, negative pressure, at the waste blood pot- to positively cite 'negative' in the claim.

8. **Claim 5** is objected to for the following: 'which is a silicon, silica, quartz, glass, polymer produced by laser, extruded polymer, or ceramics' should read—such as silicon, silica, quartz, glass, a polymer produced by a laser, an extruded polymer, or ceramics-. Correction required.

9. **Claim 6** is objected to for the following: 'control block or a hot-cold water jacket' should read -control block, a hot-cold water jacket-. Correction required.
10. **Claim 7** is objected to for the following: 'by projecting on the screen' should read – projected on the screen-. Correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 12.. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. **Claims 1-10** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As for **claim 1**, 'wherein said control unit calculates blood cell deformability and shearing force as a function of time according to pre-calculated data instead of applying instantly measured pressure data' is indefinite, for it is unclear how the control unit calculates 'blood cell deformability...time based on data received from the pressure gauge (lines 15-16)' and prints 'calculated information' and stores 'the calculated information' without applying instantly measured pressure data.

In addition, **claim 1** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission

amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the light emitting unit and the measurement unit.

Claims 2-10 are rejected for depending from a rejected base claim.

As for **claim 8**, 'wherein said image capturing unit enables capturing the diffracted images of the deformed blood cell without projecting on the screen' is indefinite, for it is unclear how this is accomplished in view of the screen and image capturing unit disclosed in **claim 1**.

As for **claim 9**, 'could use' is indefinite, for it is uncertain if what follows 'either or video camera' has to be necessarily present with the use of 'could.' In addition, it is unclear how the image capturing unit would 'use' the particular sensor array or cameras; it is unclear what is encompassed by the word 'use.'

14. **Claims 1-10** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Particularly, **claim 1** recites 'calculating the blood cell deformability, variation of the shearing force, and deformation in time based on data received from the pressure gauge' and 'wherein said control unit calculates blood cell deformability and shearing force as a function of time according to pre-calculated data instead of applying instantly measured pressure data.' which were not reasonably conveyed in the specification. Specifically, applicant's specification reiterates the control unit's function on page 3 lines 19-21; page 7 lines 5-7; and page 8, line 16-18. However, applicant's disclosure merely sets out an analysis of blood cell deformability in

regards to a calculated deformation index and a shearing force (col. 16, lines 10-15 and Fig. 7).

There does not appear to be separate deformation and cell deformability calculations, nor a calculation of shearing variation (see page 12, lines 16-24 and pages 13-14).

In regards to 'wherein said control unit calculates blood cell deformability and shearing force as a function of time according to pre-calculated data instead of applying instantly measured pressure data' applicant does not reasonably convey this on page 15 lines 9-24, for on line 13 it appears that pressures must still be monitored. In addition, applicant has not demonstrated what the relation is between pressure variation, viscosity, resistance, and vacuum pressures to arrive at a calculated pressure variation (page 15, lines 11-12). In addition, applicant has not disclosed what are the 'consistent preset conditions' on line 13 page 15. Also on lines 19-20 of page 15 it appears that the precalculated data is the precalculated shear stress from a premeasured pressure which appears to contradict calculating a 'shearing force as a function of time according to pre-calculated data.' In addition, 'instantly measured pressure data' in 'instead of applying instantly measured pressure data' would not preclude 'instantly measured pressure data' determined in a previous arbitrary blood sample test as in page 15 lines 13-18.

Claims 2-10 are rejected for depending from a rejected base claim.

Allowable Subject Matter

15. **Claims 1-10** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph and 35 U.S.C. 112 first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

As to **claim 1**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in measurement unit the control unit calculates blood cell deformability and

shearing force as a function of time according to pre-calculated data instead of applying instantly measured pressure data in combination with the rest of the limitations of **claims 1-10**.

Response to Arguments

16. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Examiner apologizes for any inconvenience but upon further consideration the rejections under 35 U.S.C. 112 first and second paragraph have been made. See above.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent 4,428,669 to Bessis; U.S. Patent 4,435,080 to Maly et al.; U.S. Patent 5,327,777 to Kaye et al.; U.S. Patent 6,193,667 to Kensey; U.S. Patent 6,322,525 to Kensey et al.; U.S. Patent 6,422,065 to Shine et al.; US 2007/0119714 to Schnelle et al.; and JP 08122328 A to Inami et al.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

- 1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and
- 2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (571) 273-8300

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr., can be reached at 571-272-2800 ext 77.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/G. J. S./
GJS
Examiner, Art Unit 2877

/Gregory J. Toatley, Jr./
Supervisory Patent Examiner, Art Unit 2877